

WALSH  
PIZZI  
O'REILLY  
FALANGA

THREE GATEWAY CENTER  
100 Mulberry Street, 15th Floor  
Newark, NJ 07102  
T: 973.757.1100  
F: 973.757.1090  
WALSH.LAW

Joel A. Pisano  
Direct Dial: (973) 757-1035  
[jpisano@walsh.law](mailto:jpisano@walsh.law)

April 17, 2020

**VIA ECF**

Honorable Tonianne J. Bongiovanni, U.S.M.J.  
United States District Court for the District of New Jersey  
Clarkson S. Fisher Federal Building & U.S. Courthouse  
402 East State Street  
Trenton, New Jersey 08608

**Re: *NewMarket v. VetPharm*, Civil Action No. 3:17-cv-01852-MAS-TJB**

Dear Judge Bongiovanni:

We represent NewMarket Pharmaceuticals LLC (“NewMarket”) in the above-referenced matter. We write to update the Court on the status of the recent arbitration between the parties per the Court’s text order of March 13, 2020. As NewMarket reported previously on March 9, 2020, the arbitrator refused to award VetPharm \$1.2 million dollars that VetPharm claimed was owed for “data point” charges and instead awarded VetPharm the nominal amount of \$345.70. In the three years it took VetPharm to secure this nominal award, NewMarket’s new animal drug application has been at a standstill and NewMarket’s patentable market exclusivity has been truncated by the same time period.

Since our last update, NewMarket has paid VetPharm the \$345.70 and VetPharm has purported to have turned over all the clinical trial study materials. However, as discussed below, there appears to be material deficiencies in what NewMarket has received and the information has not been turned over “unconditionally” as ordered by the arbitrator. [REDACTED]

[REDACTED]

**The Raw Data Received Cannot Be Meaningfully Reviewed Without Prelude’s Software**

VetPharm provided remote versions of the databases which do not have the same functionality as the full version, which is currently in the possession of third party Prelude Dynamics (“Prelude”).<sup>1</sup> According to NewMarket’s former head of research and development Dr. David Rock, an effective review of the data cannot be completed on the remote version or the incomplete hard copy paper version provided by VetPharm. NewMarket reached out to Prelude

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<sup>1</sup> Prelude is a party to this action and the electronic data capture company that VetPharm retained to host the data related to the clinical trial studies.

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to inquire about obtaining full access in compliance with the arbitrator's order so that NewMarket can perform a meaningful review. Prelude has indicated that it will cost at least [REDACTED] to reactivate the databases and provide NewMarket full access and likely much more during the duration of market approval. Since the arbitrator's awards granted NewMarket *unconditional* access to the databases, NewMarket will request, at the appropriate time and in the proper manner, a refund for any costs associated with obtaining full access to the databases from Prelude. Any costs and delay associated with NewMarket obtaining full access to the databases to perform a substantive and meaningful review equate to VetPharm imposing improper preconditions on NewMarket's review.

### **The Hard-Copy Documents Appear Incomplete**

VetPharm appears to have failed to provide all of the information necessary for NewMarket to perform a comprehensive substantive review of the hard-copy data. For example, VetPharm failed to provide NewMarket with the key for identifying which horse was dosed with a placebo and which horse was dosed with the investigational drug, an essential piece of information to unblinding the study data. Therefore, NewMarket's analysis is inherently limited and any conclusions drawn from the data are preliminary at best.

Further, VetPharm has not provided NewMarket with information and data that is in the custody and control of VetPharm's subcontractors and vendors used during the course of the studies. Only VetPharm can provide this information (or cause it to be provided) as these parties' obligations flow directly through VetPharm. Instead of providing this information in the first instance, VetPharm is now frustrating NewMarket's attempts to obtain this information by not agreeing to sign a simple acknowledgement of NewMarket's entitlement to the information. VetPharm has taken the unreasonable position that any such "request must come from and through VetPharm" on a case-by-case basis. VetPharm continues to choose the path of *most* resistance by insisting on an inefficient and cumbersome process for requesting information from these vendors and subcontractors. For Your Honor's convenience, NewMarket is attaching hereto the correspondence on this issue and NewMarket's proposed acknowledgement form.

### **VetPharm Appears to Have Misrepresented the Efficacy of the New Animal Drug**

So far, this preliminary review without the benefit of Prelude's system has revealed that the efficacy of the drug might not be the same as what was reported to NewMarket by VetPharm during the course of the studies. In an effort to obtain payment after completion of the study VetPharm CEO Denni Day represented that the efficacy of the investigational drug was 86%. [REDACTED]

NewMarket reserves all of its rights as it continues to review the databases, including in the event the CSM key is provided to NewMarket, in the event information from subcontractors is made available to NewMarket, and when NewMarket gains access to the full databases hosted by Prelude Dynamics. As NewMarket is continuing to review the databases and is waiting for VetPharm to fully comply with the terms of the Arbitrator's Order, NewMarket respectfully requests that it be permitted to submit a status update to the Court in thirty days.

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We thank the Court for its continued attention to this matter, and are available should Your Honor or Your Honor's staff require anything further or have any questions.

Respectfully submitted,

*/s Joel A. Pisano*

Joel A. Pisano

Enclosure

cc: All Counsel of Record